



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<p>(51) International Patent Classification ⁶ : A61J 1/00, 1/05, A61M 39/04</p>	<p>A1</p>	<p>(11) International Publication Number: WO 95/17873 (43) International Publication Date: 6 July 1995 (06.07.95)</p>
<p>(21) International Application Number: PCT/US94/13438 (22) International Filing Date: 18 November 1994 (18.11.94) (30) Priority Data: 08/174,530 28 December 1993 (28.12.93) US (71) Applicant: ABBOTT LABORATORIES [US/US]; CHAD 0377/AP6D-2, 100 Abbott Park Road, Abbott Park, IL 60064-3500 (US). (72) Inventors: FREDERICK, Waren, P.; 8511 Coral Road, Wonder Lake, IL 60097 (US). HELGREN, R., Hayes; 289 Banbury Road, Mundelein, IL 60060 (US). KRUGER, Robert, J.; 2260 N. Regner, McHenry, IL 60050 (US). LARKIN, Mark, E.; 419 Northgate, Lindenhurst, IL 60046 (US). (74) Agents: GORMAN, Edward, H., Jr. et al.; Abbott Laboratories, CHAD-0377/AP6D-2, 100 Abbott Park Road, Abbott Park, IL 60064-3500 (US).</p>		<p>(81) Designated States: CA, JP, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published <i>With international search report.</i></p>
<p>(54) Title: FLUID PORT RESEAL MEMBER</p> <div data-bbox="574 1213 1211 1524" data-label="Image"> </div> <p>(57) Abstract</p> <p>This invention pertains to a reseal member made of a soft elastomeric material used for sealing a fluid access port. The reseal member is inserted into the fluid access port and prevents fluids from passing therethrough. The reseal member is provided with a slit or recess, or both, that allows a user to exert minimal force to insert a blunt cannula into the reseal member to create a passage to pass fluids through the reseal member. Upon withdrawal of the blunt cannula, the reseal forms a generally fluid-tight seal so that fluids cannot pass through the reseal.</p>		

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	GB	United Kingdom	MR	Mauritania
AU	Australia	GE	Georgia	MW	Malawi
BB	Barbados	GN	Guinea	NE	Niger
BE	Belgium	GR	Greece	NL	Netherlands
BF	Burkina Faso	HU	Hungary	NO	Norway
BG	Bulgaria	IE	Ireland	NZ	New Zealand
BJ	Benin	IT	Italy	PL	Poland
BR	Brazil	JP	Japan	PT	Portugal
BY	Belarus	KE	Kenya	RO	Romania
CA	Canada	KG	Kyrgyzstan	RU	Russian Federation
CF	Central African Republic	KP	Democratic People's Republic of Korea	SD	Sudan
CG	Congo	KR	Republic of Korea	SE	Sweden
CH	Switzerland	KZ	Kazakhstan	SI	Slovenia
CI	Côte d'Ivoire	LI	Liechtenstein	SK	Slovakia
CM	Cameroon	LK	Sri Lanka	SN	Senegal
CN	China	LV	Latvia	TD	Chad
CS	Czechoslovakia	MC	Monaco	TG	Togo
CZ	Czech Republic	MD	Republic of Moldova	TJ	Tajikistan
DE	Germany	MG	Madagascar	TT	Trinidad and Tobago
DK	Denmark	ML	Mali	UA	Ukraine
ES	Spain	MN	Mongolia	US	United States of America
FI	Finland			UZ	Uzbekistan
FR	France			VN	Viet Nam
GA	Gabon				

FLUID PORT RESEAL MEMBER

TECHNICAL FIELD OF THE INVENTION

This invention relates generally to a penetrable rubber reseal member used for sealing a fluid access port of a solution container or a Y-site of an infusion tubing set, and more particularly to a reseal member
5 that can be penetrated by a blunt cannula.

BACKGROUND OF THE INVENTION

10 The use of reseal members for sealing fluid access ports, particularly in containers for intravenous solutions, is well-known in the art. Reseal members have also commonly been used to seal access ports in Y-sites of infusion tubing sets and in containers of medicaments. The reseal member prevents leakage of liquid from within the container after the
15 member is pierced by a cannula or needle to create a passage for the cannula therethrough so that fluids may be removed from the container, or be added to and mixed with the fluids in the container.

A typical prior art reseal member is comprised of a generally cylindrical, solid, rubber body. To add fluids, the reseal member is pierced
20 by a sharp cannula or needle. Sharp cannulas or needles are commonly used to penetrate the reseal member because the reseal member is thick and solid at the insertion point.

One disadvantage of using this type of prior art reseal member is possibility of needle sticks since a sharp cannula or needle is needed to
25 pierce the solid, rubber body. To overcome this disadvantage, sharp cannulas or needles are being replaced with blunt cannulas. However, a blunt cannula cannot be inserted in this type of reseal member without application of undesirably high force.

- 2 -

The present invention is intended to overcome this disadvantage as well as to present several significant advantages.

SUMMARY OF THE INVENTION

5

This invention pertains to a rubber (*e.g.*, gum rubber, silicone rubber, and the like) reseal member used for sealing a typical fluid access port, particularly in a solution container. Alternatively, the reseal member may be used in a typical injection site, such as a Y-site of an infusion tubing set.

10

The fluid access port includes a cylindrical, peripheral wall with open ends. The reseal member is positioned within the fluid access port and is fitted in fluid tight relationship with the wall. The reseal member has an end portion positioned generally at one of the open ends of the peripheral wall so that the reseal member can be penetrated by a blunt cannula so fluids may be passed into or removed from the solution container.

15

The reseal member is made of rubber and includes a region which exhibits a relatively reduced resistance to penetration by the blunt cannula, relative to the remaining area of the rubber body. In the present invention, this region may include one of several means facilitating penetration, such as an axially extending slit, a radially extending slit, an axially extending recess or a combination of these means. To help a user place the blunt cannula in the correct position for penetration, the reseal member may include a target at the exposed end of the reseal member.

20

25

The body of the reseal member may take one of several forms. In each embodiment, the reseal member takes the form of a generally cylindrical body. In one embodiment, the reseal member includes an integral annular shoulder extending from an end of the reseal member

- 3 -

with an integrally attached circular wall that extends around a portion of the exterior of the fluid port. In another embodiment, the cylindrically-shaped body of the reseal member includes an integral, annular shoulder extending from an end of the reseal member.

5 In yet another embodiment, an end of the reseal member is dished (*i.e.*, generally concave) to facilitate swabbing the end with an antimicrobial agent before the insertion of the blunt cannula. The body also includes an annular ridge for creating a radial fluid tight seal with the interior of the fluid access port.

10 This invention contemplates that a user may insert a blunt cannula through the novel reseal member of the present invention with minimal insertion force. This invention also contemplates that upon passage of a blunt cannula through the reseal member, the reseal member forms a fluid-tight seal around the cannula so as to prevent leakage of fluids
15 therethrough. It is further contemplated that upon withdrawal of the blunt cannula, the reseal member reforms a generally fluid-tight seal (by virtue of its resilience) so fluids will not pass therethrough.

These and other objects, features, and advantages of this invention are evident from the following description of a preferred embodiment of
20 this invention with reference to the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is an elevational view of a solution container with a side
25 port and a down port, each including a reseal member according to the present invention, and a tubing set which can be attached to the container by a blunt cannula and which has a Y-site including a reseal member according to the present invention;

- 4 -

Figure 2 is a perspective view of a solution container and a ferrule cap that includes a reseal member according to the present invention;

Figure 3 is a cross-sectional view of a reseal member and an access port according to a first embodiment of the invention;

5 Figure 4 is a view similar to Figure 3 illustrating a second embodiment of the invention;

Figure 5 is a view similar to Figure 3 illustrating a third embodiment of the invention;

10 Figure 6 is a view similar to Figure 3 illustrating a fourth embodiment of the invention;

Figure 7 is a view similar to Figure 3 illustrating a fifth embodiment of the invention;

Figures 8a-8b are cross-sectional views of a reseal member according to a sixth embodiment of the invention;

15 Figures 9a-9b are views similar to Figures 8a-8b illustrating a seventh embodiment of the invention; and

Figure 10 is a simplified, plan view of an exposed end of a reseal member illustrating an area that if penetrated by a blunt cannula will allow the blunt cannula to be inserted into the reseal member.

20

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

While the present invention is susceptible of embodiments in various forms, there is shown in the drawings and will hereinafter be
25 described presently preferred embodiments, with the understanding that the present disclosure is to be considered as an exemplification of the invention, and is not intended to limit the invention to the specific embodiments illustrated.

- 5 -

As illustrated in the drawings, a reseal member 20 for use in sealing a fluid access port 22 of a solution container constitutes one of the preferred embodiments of the present invention. The reseal member 20 may be penetrated by a relatively unsharpened blunt cannula 26, for example, a blunt metal or plastic cannula, to pass fluids into the container. The reseal member may alternately be configured for use, as illustrated, at a Y-site of an infusion tubing set. For those features shown in association with a side access port 22b of the solution container which are similar to the features of the down port 22, the features are designated with a "b", for example, reseal member 20b. For those embodiments illustrated in association with an access port 22c of the solution container, also referred to herein as a solution vial (Figures 8a-8b and 9a-9b), which are similar to the features of the down port 22, the features are designated with a "c", for example, reseal member 20c.

The reseal member 20 is provided with a region 24 (Figure 10) which exhibits a relatively reduced resistance to penetration by a blunt cannula 26. To pass fluids through the reseal member 20, the blunt cannula 26 is passed through the reseal member 20 and the reseal member 20 forms a fluid-tight seal around the blunt cannula 26. Upon withdrawal of the blunt cannula 26, the reseal member 20 reforms a generally fluid-tight seal and substantially prevents the passage of fluids therethrough.

The blunt cannula 26 that is used with the present invention is becoming increasingly prevalent and preferred in the healthcare industry for enhancing the efficiency with which solution are administered to patients. The cannula 26 is comprised of a long, thin shaft 28, for example, a long thin steel shaft, having an axial passage (not shown) therethrough. The end 30 of the shaft 28 is surface finished so as to create a blunt end. The outside diameter of the shaft 28 is small, approximately .050-.070 of an inch. The smooth, blunt end 30 of the cannula 26 is highly effective in

- 6 -

preventing a user from inadvertently being stuck with the end 30 of the cannula 26. Furthermore, the smooth end 30 prevents the blunt cannula 26 from tearing the interior of the reseal member 20 and desirably acts to prevent the cannula 26 from creating particulate when the blunt cannula
5 26 is passed through the reseal member 20.

The novel reseal member 20 of the present invention is used to create a fluid tight seal in a fluid access port 22, such as a port 22 in a thin, flexible container 34, typically comprising a vinyl intravenous solution container as illustrated in Figure 1, also referred to herein as an "I.V. bag."
10 It is preferable to allow fluids to be passed through the reseal member 20, so fluids may be removed from the container 34, or be added to and mixed with the fluids in the container 34. Alternatively, the reseal member 20 can be used in a solution vial 46, as shown in Figure 2, or in a Y-site 48 of an infusion tubing set, as shown in Figure 1.

Vinyl I.V. bag 34 and its attachable plastic tubing 36 are of well known constructions and as such, will not be described in detail herein. Briefly, as shown in Figure 1, the I.V. bag 34 includes two plastic sheets 38, 40 bonded together by a heat seal 42 along the edges 44 of the sheets 38, 40. Tubing 36, having an axial passage (not shown) therethrough, is attached
20 to the bag 34 by a blunt cannula 26 that is inserted through a reseal member 20. The Y-site 48 may be included along the length of the tubing 36.

In each of the embodiments of Figures 3-7, 8a-8b, and 9a-9c, the reseal member 20 (designated 20c in the embodiments of Figures 8a-8b and
25 9a-9b) has a forward end portion 50 and rearward end portion 52, each having a face 54, 56 respectively, and takes the form of a generally cylindrically shaped body 58 which defines a length and a radius. The body 58 includes a region 24 which exhibits a relatively reduced resistance to penetration by a blunt cannula 26 relative to the remaining area of the

- 7 -

forward end portion 50. This region 24 can include a preformed partial slit 60, a preformed full slit 62 which separates the body 58 into two pieces, a molded hole or recess 64, or a combination of these means, as will be described in detail herein. The molded hole or recess 64 may take one of many forms as illustrated herein without departing from the scope of the invention. When the novel reseal member 20 of the present invention is used in combination with a blunt, metal cannula 26, a user only needs to exert a minimal amount of force, for example, approximately three pounds of force, to insert the blunt cannula 26 through the reseal member 20.

The reseal member 20 is made of a soft elastomeric material, for example, a soft gum rubber or a soft synthetic elastomeric material. Since the reseal member 20 is made of this material, the body 58 of the reseal member 20 is easily displaced by the shaft 28 of the blunt cannula 26 as the cannula 26 passes through the reseal member 20.

In reference to Figure 1, the fluid access port 22 may be housed in a bottom portion 66 of the container 34, in the side of the container 34 or in a Y-site 48 of an infusion tubing set. The reseal member is typically positioned in association with a cylindrical passage 70 of the solution container or Y-site.

The fluid access port 22 is best illustrated in Figures 3-7. It will be understood that features of these embodiments of the present reseal member can be incorporated into a construction suitable for use with a Y-site, a side access port, or a solution vial. The fluid access port 22 is preferably made of a flexible, plastic material and includes a generally cylindrical peripheral wall 72 with a cylindrical, axial passage 74 therethrough. The port 22 includes an annular shoulder 76 around the circumference of the wall 72 at a predetermined distance from an end of the wall 72. The port 22 also includes an integral thin, flexible plastic

- 8 -

membrane 78 on the interior circumference of the passage 74 to provide an additional barrier means. The port 22 may also include circumferentially spaced lands 80 (only one is shown for clarity) for molding purposes.

To insert the port 22 into the passage 70, an end portion of the wall
5 74 is inserted into the passage 70 until the annular shoulder 76 generally abuts the end of the passage 70. Thus, the annular shoulder 76 prevents the fluid access port 22 from being completely inserted into the passage 70. The interior diameter of the passage 70 and the exterior diameter of the
10 fluid access port 22 are approximately the same size so as to create a fluid-tight fit when the fluid access port 22 is inserted into the passage 70. The fluid access port 22 is attached to the passage 70 by appropriate means, such as by solvent bonding to create a mechanical-like bond.

To insert the reseal member 20 into the fluid access port 22, the
15 reseal member 20 is radially compressed and driven into the fluid access port 22 a desired distance by a suitable means. Preferably, the fluid access port 22 is made of a flexible, plastic material. Thus, the port 22 flexes as the reseal member 20 is placed therein. The interior diameter of the port 22 and the exterior diameter of the reseal member 20 are approximately the same size so as to create a fluid-tight fit when the reseal member 20 is
20 inserted into the port 22.

Alternatively, as stated above, the reseal member 20b may be housed
in a side access port 22b. Side access ports are well known in the art and will only be described briefly herein. If a side access port 22b is used to house the reseal member 20b, the plastic solution container 34 includes a
25 circular aperture (not shown) in the side 38 of the container 34. The side port 20b includes a generally cylindrical peripheral wall 72b with a cylindrical, axial passage (not shown) therethrough. The side port 20b includes an integral annular shoulder 77 around the circumference of the wall 72b at the rear end of the wall 72b. The side port 22b also includes an

- 9 -

integral thin, flexible, plastic membrane (not shown) on the interior circumference of the axial passage. To attach the side port 22b to the container 34, the axial passage and the aperture are aligned and the integral annular shoulder 77 is attached to the container 34 by appropriate means, such as by heat sealing or by solvent bonding to create a mechanical-like bond.

When the blunt cannula 26 is inserted through the reseal member 20, the body 58 of the reseal member 20 is displaced around the cannula 26, and a fluid-tight seal is formed around the cannula 26 due to the natural resiliency of the rubber material. Thus, fluids are generally prevented from leaking through the reseal member 20. The diameter of a blunt cannula 26 is small and creates a small passage (not shown) through the reseal member 20 when the blunt cannula 26 is inserted. After the blunt cannula 26 has been completely inserted through the reseal member 20 and membrane 78, fluids can be passed into the container 34 or removed from the container 34, or into tubing 36 if the reseal member 20 is provided in Y-site 48. When the blunt cannula 26 is withdrawn, the reseal member 20 reforms a generally fluid-tight seal due to the natural resiliency of the elastomeric material such as rubber and fluids are substantially prevented from leaking therethrough.

As shown in Figures 4, 6 and 7, the end 82 of the fluid access port 22 may be angled inwardly around its circumference. This angled end 82 helps to insure that the reseal member 20 remains seated and effectively held captive within the port 22. Alternatively, as shown in Figures 3 and 5, the end 84 of the fluid access port 22 may be straight. Also, as shown in Figures 3, 4 and 7 the reseal member 20 may be spaced a predetermined distance from the membrane 78. Alternatively, the reseal member 20 may abut the membrane 78 as shown in Figures 5 and 6. It is to be understood that any of the embodiments may include an angled end or a straight end,

- 10 -

or may be spaced or abut the membrane without departing from the scope of this invention.

As shown in Figure 4, the region 24 that exhibits a relatively reduced resistance to penetration by the blunt cannula 26 relative to the remaining area of the end portion 50 includes a preformed axially extending slit 62. The slit 62 extends axially along the entire length and diametrically of the body 58 thus separating the body 58 into two separate pieces 86, 88. To form this slit 62, the body 58 is molded as two symmetrical halves 86, 88, by conventional molding techniques, with each half 86, 88 having a semi-circular cross-section.

The embodiment of Figure 5 is similar to the embodiment of Figure 4 except the fluid access port 22 includes a tubular, vinyl sleeve or jacket 90 on the port 22 interior that is generally cylindrical with an axial passage 92 therethrough. The interior diameter of the axial passage 92 and the exterior diameter of the reseal member 20 are approximately the same so as to create a fluid-tight seal when the reseal member 20 has been inserted into the jacket 90. The vinyl jacket 90 is bonded to the interior of the port 22 by appropriate means, such as solvent bonding. The reseal member 20 is inserted into the vinyl jacket 90 by appropriate means.

In the embodiments shown in Figures 4 and 5, since the region 24 includes a full length slit 62, the blunt cannula 26 is easily inserted through the reseal member 20. To insert the cannula 26, the user places the blunt end 30 of the cannula 26 against the reseal face 54 and pushes the cannula 26 through the reseal member 20. During insertion of the cannula 26, the body 58 compresses slightly thereby locally widening the slit 62 to allow the blunt, metal cannula 26 to pass therethrough. Due to the natural resiliency of the gum rubber, the body 58 forms a generally

- 11 -

fluid-tight seal around the shaft 28 of the cannula 26. When the cannula 26 is removed, the body 58 is decompressed and a generally fluid-tight seal is reformed in the reseal member 20.

5 It should be noted, for example, in Figures 4 and 5, that the portions of the reseal member in respect to the slit can be made to have contrasting colors or shades to facilitate location of the slit visually. A similar consideration is applicable to Figure 6 wherein, for example, ledge 95 can be transparent whereas piece 94 can be opaque.

10 In Figure 6, the region 24 again includes a preformed full slit 62 and the reseal member 20 is comprised of two separate pieces 94, 96. However, in this embodiment, the two pieces 94, 96 are nonidentical and can be formed by conventional molding techniques. The slit 62 extends axially and diametrically from the rearmost or distal end of the body 58 to a predetermined position near the exposed or proximal end of the body 58
15 and across the diameter of the body 58. At the portion of the slit 62 near the exposed end of the body 58, the slit 62 extends radially. Thus, as can be seen in Figure 6, the piece 96 generally has a cross-sectional shape of an L. Piece 96 includes a thin, solid ledge 95 at the forward end portion 50 of the reseal body 58 that overlaps piece 94.

20 In the embodiment shown in Figure 7, the reseal member 20 is made of one integral piece. and the region 24 includes a preformed partial slit 60. The partial slit 60 extends axially from the rearmost end of the reseal member 20 to a predetermined position near the exposed end of the body 58 and also across the diameter of the body 58. To form a partial slit
25 60, the two halves of the reseal body can be integrally formed, with a thin portion 98 joining the halves, as shown in Figure 7. The halves can then

- 12 -

be urged together, with the portion 98 acting as a hinge. Thin portion 98 of the reseal member 20 that is forward of the slit 60 remains as one continuous piece.

In Figure 3, the body 58 of the reseal member 20 further includes a
5 thin, integral annular wall 100 that is connected to the forward end portion 50 of the body 58 by a thin, integral shoulder 102. A circular passage or recess 104 is created between the wall 100 and the body 58. When the reseal member 20 is attached to the fluid access port 22, an end portion 106 of the port 22 is located between the annular wall 100 and the
10 body 58 with the shoulder 102 extending over the end 84 of the port 22. In this embodiment, the shoulder 102 extends over the end 84 of the port 22.

In Figure 3, the region 24 includes a molded hole or recess 64 and a preformed partial slit 60. The recess 64 extends axially from the rearmost end of the body 58 and is formed by conventional molding techniques.
15 The partial slit 60 extends forwardly of the recess 64 in the axial direction. To form the partial slit 60, the gum rubber may be prestressed on anvil and then lanced. The partial slit 60 extends partially across the diameter of the body 58 and terminates at a predetermined distance from the forward end of the body 58 thereby defining a thin, continuous piece 108 at the forward
20 end portion 50 similar to that of the embodiment shown in Figure 7.

To insert the blunt cannula 26, in the embodiments of Figures 3, 6 and 7 as shown, the user places the cannula 26 against the face 54 of the reseal member 20 and pushes the cannula 26 through the reseal member 20. The solid ledge 95 or continuous portion 98, 108 of the reseal member
25 20 must be penetrated by the blunt cannula 26, but since the reseal member 20 is made of a soft rubber material, the ledge 95 or portion 98, 108 is easily penetrated and displaced around the cannula 26. Furthermore, since the ledge 95 or continuous portion 98, 108 is thin, a user need only apply minimal force to penetrate the body 58.

- 13 -

Once the cannula 26 passes through the ledge 95 or continuous portion 98, 108, the cannula 26 travels along the partial slit 62 and then through the membrane 78. In the embodiment shown in Figure 3, the cannula 26 will also travel through the recess 64 before passing through the membrane 78. As explained hereinabove, as the cannula 26 travels through the body 58, the body 58 is compressed and then forms a generally fluid-tight seal around the cannula 26.

The reseal member 20, designated 20c in the embodiments of Figures 8a-8b and 9a-9b, may also be used in a solution vial 46 (shown in Figure 2). The access port 22c is defined by the neck portion 152 of the container which provides a generally cylindrical peripheral wall 72c within which the reseal member 20c is positioned. An opening in a ferrule cap 150, as shown in Figure 2, of the container 46 provides access to the reseal member 20c. The reseal member 20c is placed beneath the ferrule cap 150 (not shown in Figures 8b and 9b for clarity). Figures 8a and 9a illustrate the reseal member 20c prior to insertion into the associated port, while Figures 8b and 9b illustrate the reseal member 20c after compression and insertion into the access port.

The embodiment of the reseal member 20c illustrated in Figure 8a-8b includes a generally cylindrical body 58c similar to that of Figures 3-7. The body 58c also includes an annular ridge 130 along the length of the body 58c. This annular ridge 130 creates a radial fluid-tight seal with the interior of the port 22c when the body 58c of the reseal member 20c is deformed and inserted into the fluid access port 22c. The body 58c includes an annular shoulder 134 extending from the forward end portion 50c of the body 58c that abuts the end of the port 22c. The region 24c includes an axially extending shaped molded hole or recess 64c which can be formed by conventional molding techniques. The shaped molded recess 64c does not extend the full length of the body 58c. Thus, a solid, continuous portion

- 14 -

140 is forward of the recess 64c. Reseal member 20c can be formed generally as described above in connection with the reseal member shown in Figure 7, wherein the two halves of the reseal member are molded integrally with each other (Figure 8a), then urged together to define the slit-like recess 64c (Figure 8b).

The embodiment illustrated in Figures 9a-9b is similar to the reseal member 20c shown in Figures 8a-8b except that the front end portion 50c of the body 58c includes a dished (*i.e.*, concave) face 54c. The dished face 54c facilitates the swabbing of the reseal member 20c with an antimicrobial agent or the like before inserting the blunt, metal cannula 26 therethrough. The region 24c also includes an axially extending shaped molded hole or recess 64c. The shaped molded recess 64c does not extend the full length of the body 58c. Thus, a thin, solid, continuous portion 140 is forward of the recess 64c. As in the embodiment of Figures 8a-8b, the reseal member 20 is formed in a configuration as shown in Figure 9a, and is then deformed for insertion into and frictional engagement with the access port 22c, as shown in Figure 9b. A slit-like recess 64c is thus provided.

To insert the blunt cannula 26 into the embodiments shown in Figures 8a-8b and 9a-9b, the user places the cannula 26 against the face 54c of the reseal member and pushes the cannula 26 through the reseal member 20c. The solid portion 140 of the reseal member must be penetrated by the cannula 26, but since the reseal member 20c is made of a soft rubber material, the solid portion 140 is easily penetrated and displaced around the cannula 26. Furthermore, since the solid portion 140 is thin, a user need only apply minimal forces. Once the cannula 26 is inserted through the reseal member 20c, the body 58c of the reseal member 20c forms a generally fluid-tight seal around the blunt cannula 26.

- 15 -

It is contemplated the embodiments shown in Figures 4 and 5 only be used in applications such as at a Y-site 48 of an infusion tubing set which is "sold dry." That is, the reseal member 20 is preferably not wetted until the tubing set is actually used. The embodiments shown in Figures
5 3, 6,7, 8a-8b and 9a-9b may also be used in a Y-site. However, these embodiments are also suitable for "wet application" in a solution container 34, 46.

As shown in Figure 10, the region 24 creates an area 142 that, if penetrated by a blunt cannula 26, will allow the blunt cannula 26 to be
10 inserted into the reseal member 20. This is also commonly referred to as a "sweet spot." Due to the fact that the preformed slit 60, 62 or recess 64 creates this area 142, a user can insert the blunt cannula 26 into any point within the area 142. If the blunt cannula 26 is inserted into this area 142, the blunt cannula 26 will pass through the preformed slit 60, 62 or recess 64
15 (or both) to form the passage.

One feature of note is that the reseal member 20 may include a raised ridge-like projection to provide a target 144 on the front end portion
50 of the body 58, as illustrated in Figures 3, 8a-8b and 9a-9b. The target 144 aids a user in inserting a blunt cannula 26 into an area that will cause the
20 blunt cannula 26 to be passed through the preformed slit 60, 62 or recess 64 (or both) of the reseal member 20.

Another feature of note is that in the embodiments that include two molded pieces, as illustrated in Figures 4, 5 and 6, each molded piece may be made of a contrasting or different color. This aids a user in properly
25 inserting the blunt, metal cannula 26 into the reseal member 20.

While preferred embodiments have been disclosed above, it is to be understood that it is within the scope of the invention that any of the above embodiments can be easily modified for use in a side port, a down port, of a solution having a ferrule cap container or in a Y-site of an

infusion tubing set. Furthermore, it is envisioned that more than one preformed slit may be used in the reseal.

From the foregoing, it will be observed that numerous modifications and variations can be effected without departing from the true spirit and scope of the novel concept of the present invention. It is to
5 be understood that no limitation with respect to the specific embodiments is intended or should be inferred. The disclosure is intended to cover by the appended claims all such modifications as fall within the scope of the claims.

WHAT IS CLAIMED IS:

1. A reseal member readily penetrable by a blunt cannula for sealing a fluid port with a generally fluid-tight seal, said fluid port being defined by a generally cylindrical peripheral wall having open ends, said reseal member comprising:
 - 5 a elastomeric body positionable within the peripheral wall defining said fluid port in fluid tight relationship with said peripheral wall, said elastomeric body having an end portion positioned generally at one of the open ends of said peripheral wall to permit insertion of an associated relatively unsharpened blunt cannula through said reseal member,
 - 10 said elastomeric body including means defining a region of said end portion of said elastomeric body which region exhibits a relatively reduced resistance to penetration by said blunt cannula relative to the remaining area of the end portion of said elastomeric body.
2. A reseal member as defined in claim 1, wherein said fluid port is attached to a solution container.
3. A reseal member as defined in claim 1, wherein said fluid port includes a thin, flexible, puncturable membrane housed within said peripheral wall.
4. A reseal member as defined in claim 1, wherein said means defining a region of said end portion of said elastomeric body which region exhibits a relatively reduced resistance to penetration by said blunt cannula relative to the remaining area of the end portion of said elastomeric body
5 includes an axially extending slit in said body.

- 18 -

5. A reseal member as defined in claim 4, wherein said slit further extends radially.

6. A reseal member as defined in claim 4, wherein said means defining a region of said end portion of said elastomeric body which region exhibits a relatively reduced resistance to penetration by said blunt cannula relative to the remaining area of the end portion of said elastomeric body
5 further includes an axially extending recess extending from one of said ends.

7. A reseal member as defined in claim 1, wherein reseal member is comprised of two separate pieces, said pieces being of different colors.

8. A reseal member as defined in claim 1, wherein said means defining a region of said end portion of said elastomeric body which region exhibits a relatively reduced resistance to penetration by said blunt cannula relative to the remaining area of the end portion of said elastomeric body
5 further includes an axially extending recess.

9. A reseal member as defined in claim 1, wherein said means defining a region of said end portion includes a target at said end portion.

10. A reseal member as defined in claim 1, wherein said body includes an annular shoulder extending from said end portion.

11. A reseal member as defined in claim 1, wherein said elastomeric body comprises two integrally joined halves positioned adjacent each other, and joined to each other by a relatively thin portion of said body through which said blunt cannula is insertable.

12. A reseal member as defined in claim 10, wherein said end portion is dished to facilitate swabbing the end portion with an anti-microbial agent before the insertion of the blunt cannula.

13. A reseal member as defined in claim 12, wherein said body further includes an annular ridge for creating a radial fluid tight seal with the interior of said peripheral wall.

14. A reseal member readily penetrable by a blunt cannula for sealing a fluid port with a generally fluid-tight seal, said fluid port being defined by a generally cylindrical peripheral wall having open ends, said reseal member comprising:

5 a elastomeric body positionable within the peripheral wall defining said fluid port in fluid tight relationship with said peripheral wall, said elastomeric body having a first end portion positioned generally at one of the open ends of said peripheral wall to permit insertion of an associated relatively unsharpened blunt cannula through said reseal member, said
10 elastomeric body having a second end portion positioned generally within the peripheral wall,

 said elastomeric body including an annular shoulder extending from said end portion,

 said elastomeric body including a recess extending from said second
15 end portion towards said first end portion and defining a region of said end portion of said elastomeric body which region exhibits a relatively reduced resistance to penetration by said blunt cannula relative to the remaining area of the end portion of said elastomeric body.

- 20 -

15. A reseal member as defined in claim 14, wherein said body further includes an axial slit extending toward said first end portion from said recess.

16. A reseal member as defined in claim 14, wherein said fluid port is attached to a solution container.

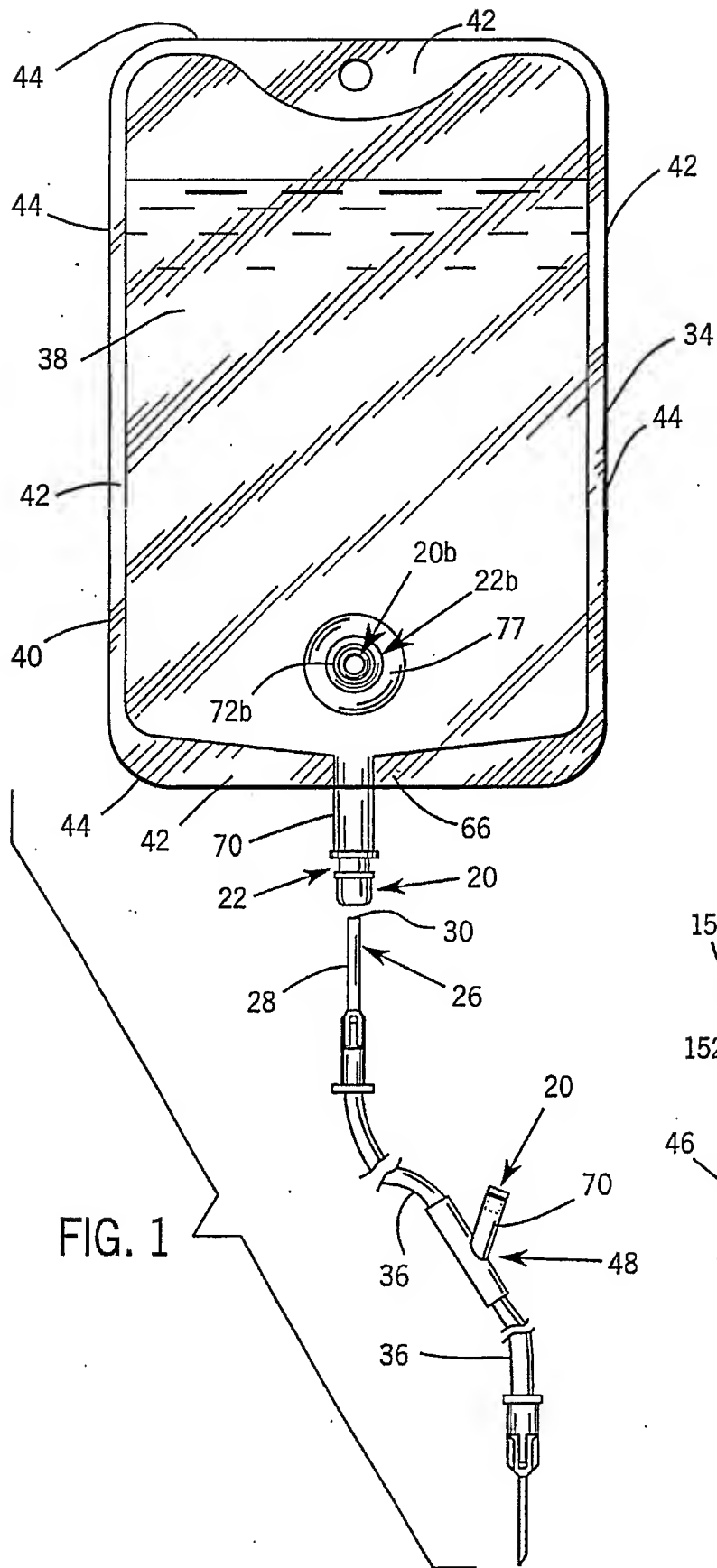


FIG. 1

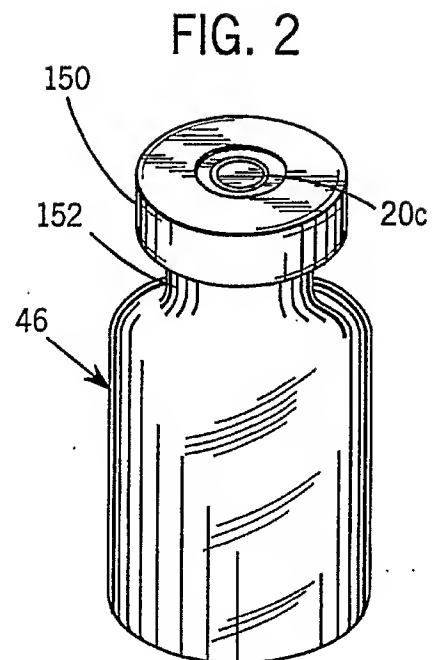


FIG. 2

FIG. 3

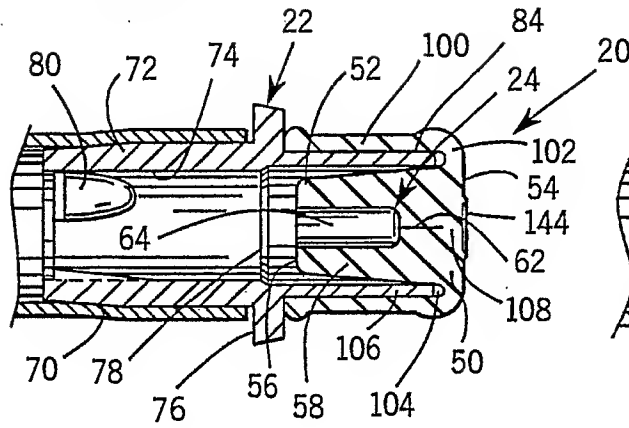


FIG. 4

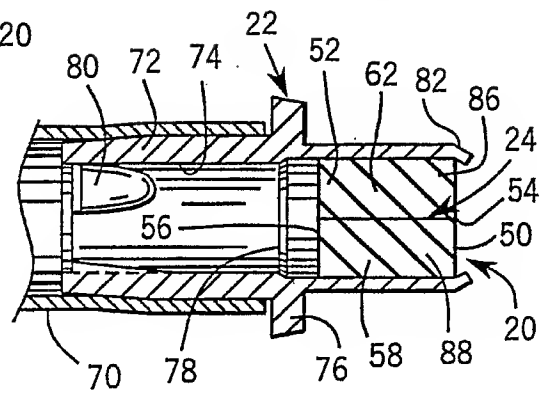


FIG. 5

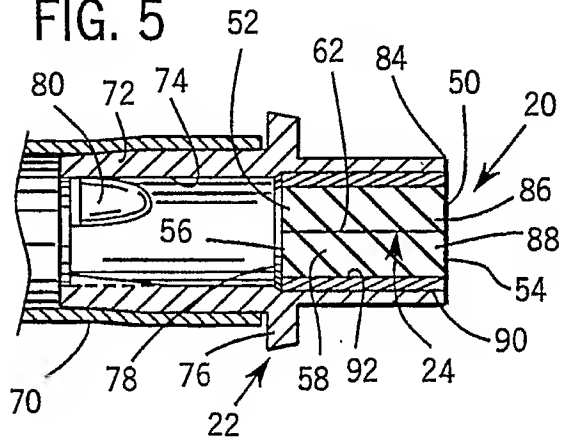


FIG. 6

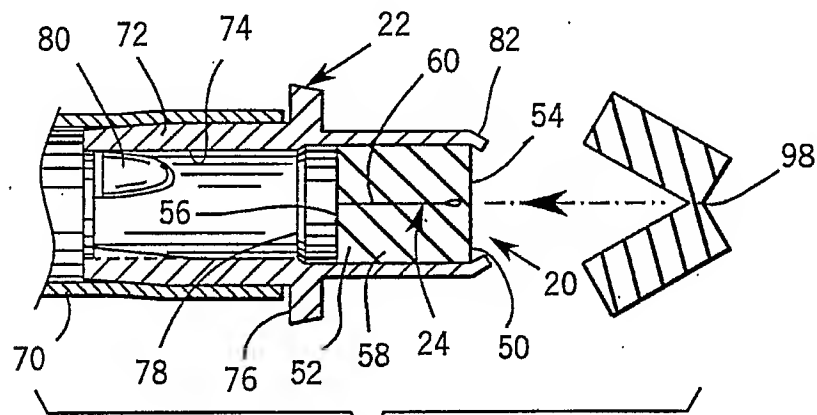
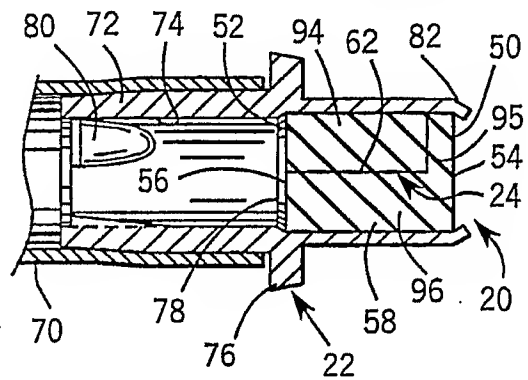


FIG. 7

FIG. 8a

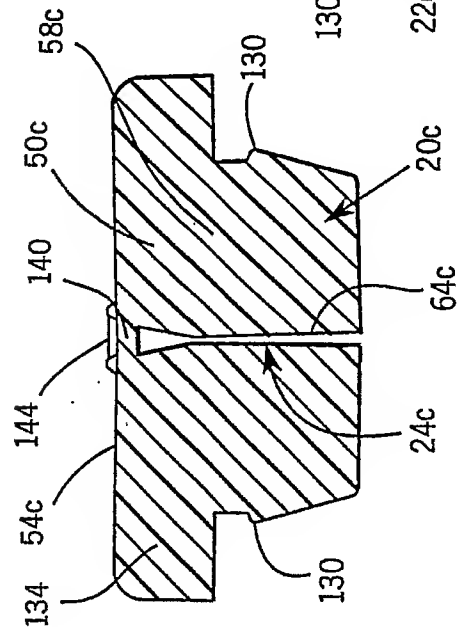


FIG. 8b

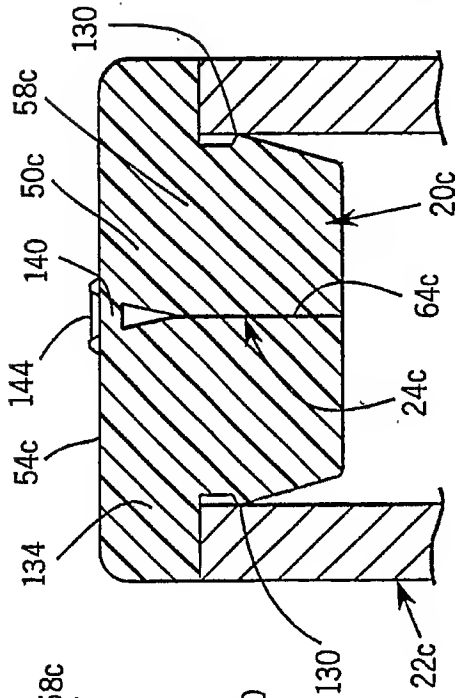


FIG. 9a

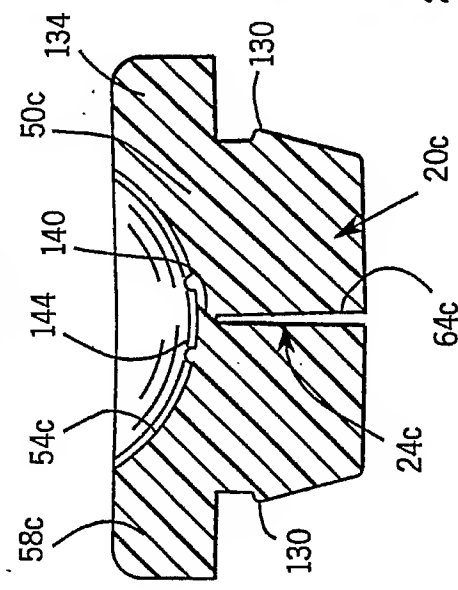


FIG. 9b

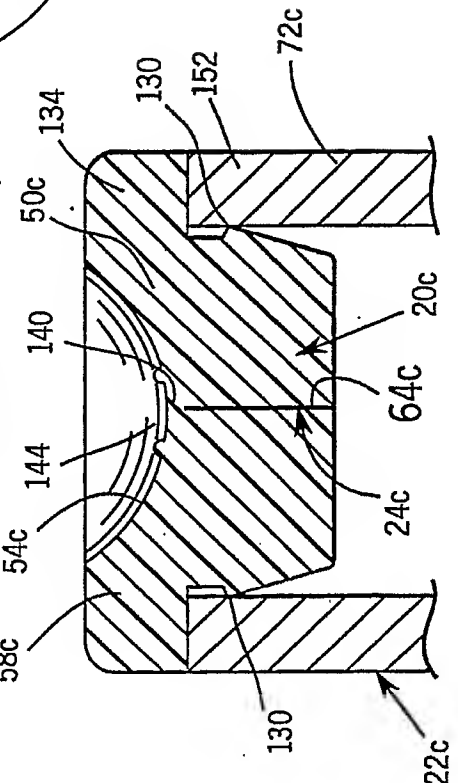
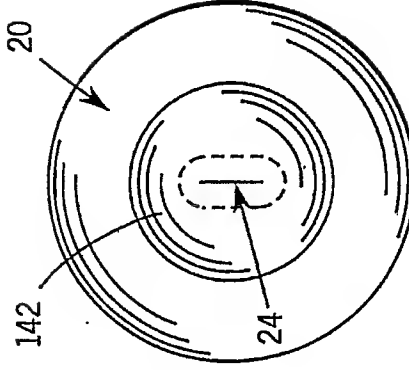


FIG. 10



A. CLASSIFICATION OF SUBJECT MATTER IPC 6 A61J1/00 A61J1/05 A61M39/04		
According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) IPC 6 A61J A61M B65D		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Electronic data base consulted during the international search (name of data base and, where practical, search terms used)		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP,A,0 544 653 (BAXTER INTERNATIONAL INC.) 2 June 1993	1,2,4,5, 11
Y	see column 9, line 49 - line 54; figures 9,16	3,6, 8-10, 12-14
P,Y	--- WO,A,94 03373 (THE WEST COMPANY INC.) 17 February 1994 see figures -----	3,6, 8-10, 12-14
<div style="display: flex; justify-content: space-between;"> <input type="checkbox"/> Further documents are listed in the continuation of box C. <input checked="" type="checkbox"/> Patent family members are listed in annex. </div>		
* Special categories of cited documents :		
<div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> </div> <div style="width: 45%;"> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"&" document member of the same patent family</p> </div> </div>		
Date of the actual completion of the international search	Date of mailing of the international search report	
13 February 1995	09.03.95	
Name and mailing address of the ISA	Authorized officer	
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+ 31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+ 31-70) 340-3016	Godot, T	

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP-A-0544653	02-06-93	AU-B- 648668	28-04-94
		AU-A- 1738592	30-07-92
		AU-A- 3039189	11-08-89
		AU-B- 5522094	23-06-94
		AU-B- 5522194	23-06-94
		DE-D- 68916876	25-08-94
		DE-D- 68919861	19-01-95
		EP-A- 0354947	21-02-90
		EP-A- 0544654	02-06-93
		EP-A- 0544655	02-06-93
		JP-T- 2502976	20-09-90
		JP-B- 5032071	14-05-93
		WO-A- 8906553	27-07-89
		US-A- 5135489	04-08-92
		US-A- 5100394	31-03-92
		US-A- 5167648	01-12-92
		US-A- 5171234	15-12-92
		US-A- 5158554	27-10-92
		US-A- 5188620	23-02-93
		US-A- 5211638	18-05-93
		CA-A- 1330412	28-06-94
<hr/>			
WO-A-9403373	17-02-94	AU-B- 4999793	03-03-94
<hr/>			